



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,587	01/04/2007	Andrew Lynn	BOUL 3506	3072
321	7590	02/22/2010	EXAMINER	
SENNIGER POWERS LLP 100 NORTH BROADWAY 17TH FLOOR ST LOUIS, MO 63102			ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER
			1652	
			NOTIFICATION DATE	DELIVERY MODE
			02/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No. 10/595,587	Applicant(s) LYNN ET AL.	
	Examiner HOPE A. ROBINSON	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/19/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. The Amendment filed in response to the Office Action mailed June 23, 2009 on October 19, 2009 has been received and entered.

Claim Disposition

2. Claims 1-57 are canceled. Claim 88 has been added. Claims 58-88 are pending and are under examination.

Information Disclosure Statement

3. The Information Disclosure Statement filed on October 19, 2009 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Claim Objection

4. Claims 84 and 87 are objected to because of the following informalities:

Art Unit: 1652

For clarity and precision of claim language it is suggested that claim 84 is amended to read, "A precursor material comprising a triple co-precipitate consisting essentially of collagen, brushite and a glycosaminoglycan.

For clarity and precision of claim language it is suggested that claim 87 is amended to read, "A biomaterial comprising a triple co-precipitate [[particles]] of [[one or more]] a calcium phosphate [[materials]], collagen and [[one or more]] a glycosaminoglycan[[s]], wherein said collagen and said [[one or more]] glycosaminoglycan[[s]] are crosslinked [[and]] to form a matrix[[,]]; said [[particles of]] calcium phosphate [[material are]] is dispersed in said matrix[[,]] ; and said calcium phosphate [[material]] is selected from [[one or more]] the group consisting of brushite, octacalcium phosphate and [[/or]] apatite.

Correction is required.

Claim Rejections - 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 58-88 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a process for the production of a composite material comprising collagen, brushite and one or more glycosaminoglycans...precipitating the collagen, the brushite and the one or more glycosaminoglycans together from the aqueous solution to form a triple coprecipitate". The claimed method is missing an essential step with respect to how the brushite is formed before it is precipitated as a triple co-precipitate. Further, the claim language establishes that the collagen, brushite and glycosaminoglycan is precipitated together, however, the instant specification at paragraph [0012] defines a "triple co-precipitate" as precipitating as "substantially the same time". There is no indication in the specification as to what is construed as "substantially the same", for example, five minutes, 30 minutes or 60 minutes etc. Thus, the claimed invention is not adequately described. Moreover, claim 58 is drawn to a genus of glycosaminoglycans. It is noted that claim 64 recites a list, however, independent claim 58 needs to stand on its own.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by

Art Unit: 1652

functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Moreover, *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993).

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 58-88 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claims 58, 73, 84, 86, 87 and the dependent claims hereto are indefinite for the recitation of "one or more glycosaminoglycans" in a triple precipitate, as this can be construed as more than three products being precipitated. It is suggested that a specific one is listed in the claim or that the language refers to "a glycosaminoglycan".

Claims 58, 65-67, 69-72 and 88 lack clear antecedent basis for the recitation of "the aqueous solution" and "the solution", respectively.

Claims 73 and 74 lack clear antecedent basis for "at least some of the brushite". In addition, the objective of the claim is a process for the production of a composite biomaterial comprising "collagen, octacalcium phosphate and glycosaminoglycans", however, the method step indicate that a composite material comprising collagen, brushite and glycosaminoglycan is provided and at least some of the brushite is converted to octacalcium phosphate, therefore, the composite biomaterial would then consists of "collagen, glycosaminoglycan, octacalcium phosphate and the remaining

Art Unit: 1652

brushite. Therefore, there is no nexus between the preamble of the claim and the end product. See also claim 78 with similar language.

Claim 75 is indefinite for the recitation of "said aqueous solution being at or above the pH at which octacalcium phosphate becomes thermodynamically more stable than brushite" as no pH is provided or any indication that the solution is acidic or basic, both of which have a wide range of pH.

Response to Arguments

7. Applicant's comments have been considered in full. Note that the rejections of record are withdrawn, therefore applicant's arguments are moot and will not be addressed herein. Note however, that new grounds of rejections/objections have been instituted for the reasons set forth above.

Conclusion

8. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 6:30 p.m.

Art Unit: 1652

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652